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Docket No.: H 4494 PCT/US
 RE: Kleen et al.
 Application No.: 10/088,432
 Examiner: Eisa B. Elhilo
 Grp./Art Unit: 1751
 Confirmation No.: 1770

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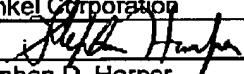
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		Application Number	10/088,432
		Filing Date	May 31, 2002
		First Named Inventor	Astrid KLEEN
		Art Unit	1751
		Examiner Name	Eisa B. Elhilo
Total Number of Pages in This Submission	23	Attorney Docket Number	H 4494 PCT/US

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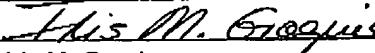
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Kleen, et al.

Confirmation No.: 1770

Application No.: 10/088,432

Group Art Unit: 1751

Filing Date: May 31, 2002

Examiner: Eisa B. Elhilo

For: METHOD FOR RESTRUCTURING KERATIN FIBERS

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Sir:

APPELLANT'S BRIEF PURSUANT TO 37 C.F.R. § 41.37

This brief is in support of Appellant's appeal from the rejections of claims 13-27 in the Final Office Action dated November 3, 2004. Appellant filed a Notice of Appeal on February 28, 2005.

1. REAL PARTY IN INTEREST

The real party in interest is Henkel Kommanditgesellschaft auf Aktien (Henkel KGaA), by virtue of the assignment recorded 7 June 2002, at Reel 012980, Frame 0942.

2. RELATED APPEALS AND INTERFERENCES

None.

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3. STATUS OF THE CLAIMS

Claim 1	Canceled	Claim 17	Rejected and On Appeal
Claim 2	Canceled	Claim 18	Rejected and On Appeal
Claim 3	Canceled	Claim 19	Rejected and On Appeal
Claim 4	Canceled	Claim 20	Rejected and On Appeal
Claim 5	Canceled	Claim 21	Rejected and On Appeal
Claim 6	Canceled	Claim 22	Rejected and On Appeal
Claim 7	Canceled	Claim 23	Rejected and On Appeal
Claim 8	Canceled	Claim 24	Rejected and On Appeal
Claim 9	Canceled	Claim 25	Rejected and On Appeal
Claim 10	Canceled	Claim 26	Rejected and On Appeal
Claim 11	Canceled	Claim 27	Rejected and On Appeal
Claim 12	Canceled	Claim 28	Allowed
Claim 13	Rejected and On Appeal	Claim 29	Allowed
Claim 14	Rejected and On Appeal	Claim 30	Allowed
Claim 15	Rejected and On Appeal	Claim 31	Allowed
Claim 16	Rejected and On Appeal		

4. STATUS OF AMENDMENTS

Appellant filed a reply (including certain claim amendments) to the Final Office action on January 14, 2005, however, the Advisory Action dated February 1, 2005, indicated that the proposed amendments would not be entered. Thus, the claims have not changed subsequent to the Final Office Action mailed November 3, 2004.

Since the amendment was not entered, Appellant wishes to point out that it has no effect on the prosecution of the case. In fact, Appellant repudiates the amendments, which would have unnecessarily given up claim scope to which Appellant is entitled, and relies on the arguments made below.

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5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to restructuring keratin fibers that have been damaged, for example, by grooming, certain treatments, and environmental influences.

See Appellant's specification at page 1, line 22 to page 2, line 5. Restructuring is a "reduction in the damage done to keratin fibers." Id., page 1, lines 22-23. Restructuring can be determined subjectively, through perception of improved luster, feel, and combability. Id., page 1, line 25 - page 2, line 1. Qualitatively, "successful restructuring can be physically manifested as an increase in melting point ...". Id., page 2, lines 1-4.

To this end, independent claim 13 recites "[a] process for restructuring keratin fibers comprising applying to keratin fibers (a) at least one enzyme having transglutaminase activity; and (b) at least one active substance having substrate activity for the enzyme." *Emphasis added.* In the claimed process, both enzyme and substrate are applied to the fibers. This is significant, because the combination results in a synergistic effect in raising the melting point of the fibers as compared to merely treating the fibers with enzyme or substrate alone. *Appellant's specification at page 20, line 1 – page 21, line 16, e.g., page 21, lines 15-16.*

The present invention also relates to setting hair for special styling effects. *Appellant's specification at page 2, lines 10-13; see also page 19, lines 19-22.* Independent claim 24 recites "[a] process for setting keratin fibers comprising (a) applying to keratin fibers at least one enzyme having transglutaminase activity and at least one active substance having substrate activity for the enzyme; and (b) setting the

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keratin fibers." *Emphasis added.*

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 13, 15-20, and 24-26 stand rejected as obvious under 35 U.S.C. §103(a) over U.S. Patent No. 6,274,364 (hereinafter the "Bernard reference").

Claims 14, 21-23, and 27 stand rejected as obvious under 35 U.S.C. §103(a) over the Bernard reference in view of U.S. Patent No. 6,051,033 (hereinafter the "McDevitt reference").

Appellant submits that the Examiner has failed to establish a proper *prima facie* case of obviousness in either rejection.

7. ARGUMENT

The Examiner has not demonstrated that Claims 13, 15-20, and 24-26 are unpatentable for obviousness under 35 U.S.C. §103(a) over the Bernard reference.

Claim 13

In making the rejection, the Examiner has ignored the admonitions of MPEP §2141, which states that:

When applying 35 U.S.C. 103, the following tenets of patent law *must be adhered to*:

- (A) The claimed invention **must be considered as a whole**;
- (B) The references must be considered as a whole and **must suggest the desirability and thus the obviousness of making the combination**;
- (C) The references must be viewed without the benefit of impermissible

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hindsight vision afforded by the claimed invention; and
(D) Reasonable expectation of success is the standard with which obviousness
is determined.

The Examiner failed to adhere to these basic tenets, and has failed to establish a *prima facie* case of obviousness. The rejection is therefore improper.

Claim 13 recites "[a] process for restructuring keratin fibers comprising applying to keratin fibers (a) at least one enzyme having transglutaminase activity; and (b) at least one active substance having substrate activity for the enzyme." *Emphasis added.* As is evident, this claim is for a process for restructuring keratin fibers. Based on Appellant's examples, the transglutaminase enzyme and substrate do not appear to have much effect on the melting point of fibers when only one is applied, but when both transglutaminase enzyme and substrate are applied, they have a synergistic effect, evidencing highly desirable restructuring ability. See *Appellant's specification*, page 21, lines 8-16. Thus, considering the invention as a whole requires that the claim be read as a process and that both steps be performed.

Nonetheless, the Examiner has repeatedly erred by stating "such a composition is expressly suggested by Bernard et al disclosure and therefore is an obvious formulation" (*First Office action*, page 4, lines 18-19) and "this is an obvious formulation" (*Final Office action*, page 3, lines 3-4). Clearly, such statements are irrelevant to whether the claimed process is obvious. The Examiner has impermissibly boiled the invention down to a gist by comparing formulations, not the claimed process. See MPEP §2141.02. The rejection is improper.

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Also, assuming *arguendo* that the formulations are identical, section 2142.02 of the MPEP states: "[o]bviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established."

The Bernard reference discloses a newly isolated protease. The protease finds use in "promoting desquamation." *Id.*, col. 1, lines 19-20. "Desquamate" means to peel off in scales. *Merriam-Webster Dictionary Online* (www.m-w.com). Appellant cannot understand how applying a desquamating agent to remove undesirable excess skin renders the presently claimed invention obvious, as a worker of ordinary skill in the art concerning with developing an improved process for restructuring keratin fibers would have had no reason to look to the teachings of the Bernard reference for guidance in this endeavor. The Examiner's failure to consider the reference *as a whole* has led to this erroneous conclusion.

Apparently, the Examiner is of the view that it would be obvious to pick various components taught in the Bernard reference and employ such components so as to arrive at Appellant's claimed process. However, this is impermissible without considering context. The Bernard reference teaches that "[n]umerous pathological conditions of the skin are characterized by the production of a thick horny layer and by an abnormal desquamation, namely, by hyperkerat[osis]. The latter may occur on any anatomical skin area...". *Id.*, col. 2, lines 64-67; emphasis added. If abnormal skin cell build-up can occur anywhere there is skin, it is not surprising for the Bernard reference to mention **scalp care compositions** incorporating the protease described in the reference, for example shampoo, hair setting lotion, and "restructuring lotions for the hair." *Id.*, col. 8,

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lines 15-24, since such compositions would during use be contacted with the skin of the scalp.

The Bernard reference states that transglutaminase is a **protease activator**, and so can optionally be added to the Bernard reference's composition to activate the protease. *Id.*, col. 7, lines 17-22. Likewise, the Bernard reference teaches that certain "protein hydrolysates" are **protease activators**. *Id.*, col. 6, lines 35-43. Appellant notes that the Examiner has not explained how the Bernard reference provides a motivation or suggestion for selecting substrates of transglutaminase. In fact, the **transglutaminase of the Bernard reference is present for the purpose of increasing the desquamation properties**:

Transglutaminases E and K are both involved in the formation of the **horny envelope** by bridging numerous proteins to one another, ... Accordingly, if the activity of the transglutaminases is increased either by the provision of transglutaminase activator, or by the direct provision of transglutaminase, the quantity of constituent proteins of the horny envelope is then increased, which proteins are trapped in the formation of this envelope under the influence of transglutaminase. The stratum corneum is in this case deprived of its endogenous proteins, including in particular the cystatins. The disappearance of the cystatins from the epidermis and more particularly from the stratum corneum then has the effect of releasing the cyssteine proteases whose activity is then increased, which has the effect of reducing intercorneocyte cohesion and therefore of promoting desquamation. ... Exemplary protease activators include glycerol, urea, EDTA, transglutaminase and reducing agents.

col. 6, line 62 – col. 7, line 22; emphasis added. Since the Bernard reference encourages the above-described cascade that results when transglutaminase ties up cystatins in the epidermis (see col. 7, lines 4-16), if anything, the Bernard reference reaches away from Appellant's limitation of applying "at least one active substance having substrate activity for the enzyme." For example, if transglutaminase was added, and a substrate for the

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transglutaminase was also added, the transglutaminase would have a reduced role in desquamation. Therefore, there is no motivation to add a transglutaminase substrate, since this would interfere with the stated objective of the Bernard reference compositions (i.e., to promote desquamation).

The Bernard reference would be highly relevant to the patentability of a process to peel away undesirable skin layers. However, one properly considering the reference *as a whole* would not have found it relevant to Appellant's Claim 13, which is directed to a "process for restructuring keratin fibers ...". Nothing in the Bernard reference even suggests or concerns a process that leads to improved luster, feel, combability, or an increase in melting point, of hair, which Appellant describes as indicative of a reduction in the damage done to keratin fibers. In fact, the Bernard reference is completely silent on the effect of its composition on hair or other keratin fibers. More pertinently, there is no teaching or suggestion that a transglutaminase enzyme and a substrate for such enzyme would, when applied to keratin fibers, interact synergistically to advantageously restructure such fibers.

It is simply not enough that the composition is disclosed (see discussion on impermissible hindsight below), the reference must teach the *desirability* of doing what the patent applicant has done. There is no teaching in the Bernard reference that would guide a skilled worker toward a process for restructuring keratin fibers or of applying both recited components to keratin fibers in order to improve the structure of those fibers.

As noted above, while the Bernard reference may disclose certain components

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that are utilized in Appellant's claimed process, there is no pertinent teaching in the Bernard reference that leads toward that process. Without any suggestion from the Bernard reference to do what the Appellant has done, the invention can only be arrived at by using impermissible hindsight. Thus, a *prima facie* case of obviousness has not been established. See MPEP §2143.

Appellant is equally baffled by the Examiner's rationale for the rejection:

... it would have been obvious ... to apply such a composition to the keratin fibers by using such a method, because such a composition that comprises transglutaminase enzymes and substance having substrate activity of protein hydrolyze falls within the scope of those taught by Bernard et al. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success, because such a composition is expressly suggested by Bernard et al disclosure and therefore is an obvious formulation.

Office action dated March 9, 2004, page 4.

What possible expectation of success could one in the art have had? Nothing in the Bernard reference even suggests a process that leads to improved luster, feel, combability, or an increase in melting point, of hair, which Appellant describes as indicative of a reduction in the damage done to keratin fibers.

Additionally, consider the Bernard reference's teaching that the transglutaminase and protein hydrolyzate are both present as protease activators (i.e., their intended function is to activate protease). It would make no sense to remove protease and retain these activating components. Without the protease, there would be no reason apparent from the Bernard reference to retain either transglutaminase or protein hydrolyzate in the composition. Moreover, it would destroy the function of the Bernard reference composition as a desquamating composition. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no

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suggestion or motivation to make the proposed modification." MPEP §2143.01.

Appellant submits that a *prima facie* case of obviousness has not been established, as the Bernard reference neither discloses, teaches, or suggests the claimed process.

Claim 15

Claim 15 recites "[t]he process of claim 13 wherein the active substance having substrate activity comprises at least one protein or protein hydrolyzate, or combinations thereof." For the reasons apparent with regard to the base claim, no *prima facie* case of obviousness has been established. The Bernard reference, as previously explained, *teaches away* from adding a substrate for transglutaminase. Additionally, the Examiner **has provided no motivation or suggestion for selecting these particular substrates of transglutaminase.** There are protein hydrolyzates in the Bernard reference, but they are present as protease activators. *Id.*, col. 6, lines 35-43. In the absence of a suggestion or motivation, no *prima facie* case of obviousness can be established.

Claim 16

Claim 16 recites "[t]he process of claim 13 wherein the active substance having substrate activity comprises at least one protein or protein hydrolyzate of elastin, collagen, keratin, silk, soya, almond, pea, alga, potato, or wheat, or combinations thereof." For the reasons apparent with regard to the base claim, no *prima facie* case of obviousness has been established. The Bernard reference *teaches away* from adding a substrate for transglutaminase. Additionally, the Examiner **has provided no motivation or suggestion for selecting these particular substrates of transglutaminase.** In the

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absence of a suggestion or motivation, no *prima facie* case of obviousness can be established.

Claim 17

Claim 17 recites "[t]he process of claim 16 wherein the active substance comprises casein, soya protein or wheat protein, or combinations thereof." For the reasons apparent with regard to the base and intervening claims, no *prima facie* case of obviousness has been established. The Bernard reference *teaches away* from adding a substrate for transglutaminase. Additionally, the Examiner has provided no motivation or suggestion for selecting these particular substrates of transglutaminase. While casein is disclosed in the Bernard reference, it is part of an ENZCHECK[®] kit, "a rapid and simple method of measuring the protease activities," with casein as the protease substrate. *Id.*, col. 11, lines 41-53. There is no mention of combining casein with transglutaminase. Casein is not even part of the Bernard reference's composition. In the absence of a suggestion or motivation, a *prima facie* case of obviousness cannot be established.

Claim 18

Claim 18 recites "[t]he process of claim 13 wherein the active substance having substrate activity comprises a substance synthetically functionalized with an H₂N-R group or an H₂N-(CO)-R' group, wherein R and R' represent an unbranched C₁₋₈ alkylene group." For the reasons apparent with regard to the base claim, no *prima facie* case of obviousness has been established. The Bernard reference *teaches away* from adding a substrate for transglutaminase. Additionally, the Examiner has provided no motivation

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or suggestion for selecting these particular substrates of transglutaminase. The Examiner has failed to point out where in the Bernard reference a teaching or suggestion to utilize a substrate bearing this specific type of "synthetically functionalized" group may be found. In the absence of a suggestion or motivation, no *prima facie* case of obviousness can be established.

Claim 19

Claim 19 recites "[t]he process of claim 18 wherein the synthetically functionalized substance has at least one $\text{H}_2\text{N}-(\text{CH}_2)_4$ group." For the reasons apparent with regard to the base and intervening claims, no *prima facie* case of obviousness has been established. The Bernard reference *teaches away* from adding a substrate for transglutaminase. Additionally, the Examiner has provided no motivation or suggestion for selecting these particular substrates of transglutaminase. The Examiner has failed to point out where in the Bernard reference instances of substrates bearing a "synthetically functionalized" group of this type are taught or suggested. In the absence of a suggestion or motivation, no *prima facie* case of obviousness can be established.

Claim 20

Claim 20 recites "[t]he process of claim 18 wherein the synthetically functionalized substance has at least one $\text{H}_2\text{N}-(\text{CO})-\text{CH}_2-\text{CH}_2$ group." For the reasons apparent with regard to the base and intervening claims, no *prima facie* case of obviousness has been established. The Bernard reference *teaches away* from adding a substrate for transglutaminase. Additionally, the Examiner has provided no motivation

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or suggestion for selecting these particular substrates of transglutaminase. The Examiner has failed to point out instances of "synthetically functionalized" groups. In the absence of a suggestion or motivation, no *prima facie* case of obviousness can be established.

Claim 24

No *prima facie* case of obviousness has been established against independent claim 24, which recites: "A process for setting keratin fibers comprising (a) applying to keratin fibers at least one enzyme having transglutaminase activity and at least one active substance having substrate activity for the enzyme; and (b) setting the keratin fibers." As §2143 of the MPEP states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure.

First, the Examiner has repeatedly erred by stating "such a composition is expressly suggested by Bernard et al disclosure and therefore is an obvious formulation" (*First Office action*, page 4, lines 18-19) and "this is an obvious formulation" (*Final Office action*, page 3, lines 3-4). Such statements are irrelevant to whether the claimed process is obvious. Also, assuming *arguendo* that the formulations were identical, section 2142.02 of the MPEP states: "[o]bviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later

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established." The Examiner has impermissibly boiled the invention down to a gist by comparing formulations, not the claimed process, and therefore the rejection is improper. See MPEP §2141.02.

Second, the Bernard reference is limited to a protease and processes to peel away undesirable skin layers. Nothing in the Bernard reference suggests a process for setting keratin fibers. In fact, the Bernard reference is completely silent on the effect of its composition on hair or other keratin fibers. Additionally, the Examiner has provided no motivation or suggestion for selecting substrates of transglutaminase. If anything, the Bernard reference *teaches away* from Appellant's limitation of applying "at least one active substance having substrate activity for the enzyme." The Bernard reference encourages the cascade that results when transglutaminase ties up cystatins in the epidermis. See col. 7, lines 4-16. If transglutaminase was added, and substrate was added, the transglutaminase would have a reduced role in desquamation. *Id.* Therefore, there is no motivation to add any transglutaminase substrate. It is simply not enough that the composition is disclosed, the reference must teach the *desirability of doing what the patent applicant has done.*

Finally, what possible expectation of success could one in the art have had? Nothing in the Bernard reference even suggests a process for setting hair. Additionally, consider the Bernard reference's teaching that the transglutaminase and protein hydrolyzate are present as protease activators. It would make no sense to remove protease and retain these activating components. Moreover, it would destroy the function of the Bernard reference composition as a desquamating composition. "If proposed

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modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP §2143.01.

Appellant submits that no *prima facie* case of obviousness was established as the Bernard reference neither discloses, teaches, nor suggests the claimed process.

Claim 25

Claim 25 recites "[t]he process of claim 24 wherein the active substance having substrate activity comprises at least one protein or protein hydrolyzate of elastin, collagen, keratin, silk, soya, almond, pea, alga, potato, or wheat, or combinations thereof." For the reasons apparent with regard to the base claim, no *prima facie* case of obviousness has been established. The Bernard reference *teaches away* from adding a substrate for transglutaminase. Additionally, the Examiner has provided no motivation or suggestion for selecting these particular substrates of transglutaminase. In the absence of a suggestion or motivation, no *prima facie* case of obviousness can be established.

Claim 26

Claim 26 recites "[t]he process of claim 25 wherein the active substance comprises casein, soya protein or wheat protein, or combinations thereof." For the reasons apparent with regard to the base and intervening claims, no *prima facie* case of obviousness has been established. The Bernard reference *teaches away* from adding a substrate for transglutaminase. Additionally, the Examiner has provided no motivation

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or suggestion for selecting these particular substrates of transglutaminase. While casein is disclosed in the Bernard reference, it is part of an ENZCHECK™ kit, "a rapid and simple method of measuring the protease activities," with casein as the *protease substrate*. *Id.*, col. 11, lines 41-53. There is no mention of combining casein with transglutaminase. In the absence of a suggestion or motivation, no *prima facie* case of obviousness can be established.

The Examiner has not demonstrated that claims 14, 21-23, and 27 are rejected under 35 U.S.C. §103(a) over the Bernard reference in view of the McDevitt reference.

Claim 14

Claim 14 enjoys the limitations of its base claim, Claim 13, with the added limitation that "the enzyme having transglutaminase activity comprises a calcium-independent transglutaminase." Aside from its above-noted limitations, the Bernard reference teaches that its protease activating transglutaminases are calcium dependent. *Id.*, col. 6, lines 52-54. Thus, the Examiner provides the McDevitt reference to supply the deficiency of the Bernard reference, but the references cannot be combined.

Section 2143.01 of the MPEP states "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art¹." The Bernard

¹ MPEP §2143.01 specifically states: "[t]he level of skill in the art cannot be relied upon to provide the suggestion to combine references."

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reference relates to a desquamating composition and process. The Examiner's allegation that the Bernard reference teaches "a hair dyeing composition," while not a complete mischaracterization (in view of col. 8, lines 18-20) is not entirely accurate. The passage is directed to many examples of compositions for care of the scalp (col. 8, line 16), with the common thread being the desquamating properties provided by the protease.

On the other hand, the McDevitt reference is limited to a textile method for "treating wool, wool fibers or animal hair with a transglutaminase and a proteolytic enzyme." *Id.*, col. 1, lines 14-16. For example, the McDevitt reference states "[t]he method of the invention can be used with **wool or animal hair material in the form of top, fiber, yarn, or woven or knitted fabric**. The enzymatic treatment can also be carried out on **loose flock or on garments** made from wool or animal hair material." *Id.*, col. 4, lines 62-66; *emphasis added*. Thus, the problems are vastly different.

The teachings are also mutually exclusive. The Bernard reference has no teachings of the effect on keratin fibers. If there is any doubt that the McDevitt reference is limited to textile processing conditions, Appellant refers to the Examples, where each example has the wool/animal hair sample subjected to "a ten minute heating gradient up to 80°C, then held at that temperature for ten minutes...". *Id.*, at col. 8, lines 56-58; col. 9, lines 16-18, and lines 44-46; col. 10, lines 6-7, and 38-40, and see col. 10, lines 66-67 and col. 12, lines 17-18; *emphasis added*. That is 176 °F, well above the **temperature where burns occur**. This *teaches away* from the Bernard reference, with its skin treating compositions and processes. It is improper to combine references where the references teach away from their combination. MPEP §2145. Thus, the

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rejection is improper.

Claim 21

Claim 21 recites "[t]he process of claim 13 wherein the enzyme having transglutaminase activity and the active substance having substrate activity are applied simultaneously to the keratin fibers." As noted above, the Bernard reference and the McDevitt reference teach away from combination, and thus the rejection is improper.

Claim 22

Claim 22 recites "[t]he process of claim 13 wherein the enzyme having transglutaminase activity, and the active substance having substrate activity are applied successively in any order." As noted above, the Bernard reference and the McDevitt reference teach away from combination, and thus the rejection is improper.

Claim 23

Claim 23 recites "[t]he process of claim 13 wherein the enzyme having transglutaminase activity is contacted with the keratin fibers for a contact time of 3 minutes to 120 minutes." As noted above, the Bernard reference and the McDevitt reference teach away from combination, and thus the rejection is improper.

Claim 27

Claim 27 recites "[t]he process of claim 26 wherein the enzyme having transglutaminase activity comprises a calcium-independent transglutaminase." As noted above, the Bernard reference and the McDevitt reference teach away from combination,

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and thus the rejection is improper.

For the foregoing reasons, the Examiner has failed to establish his *prima facie* burden, and thus the rejections are improper. The foregoing arguments have demonstrated that the claims are separately patentable. The claims thus do not stand or fall together.

8. CLAIMS APPENDIX

13. (Rejected and On Appeal) A process for restructuring keratin fibers comprising applying to keratin fibers
 - (a) at least one enzyme having transglutaminase activity; and
 - (b) at least one active substance having substrate activity for the enzyme.
14. (Rejected and On Appeal) The process of claim 13 wherein the enzyme having transglutaminase activity comprises a calcium-independent transglutaminase.
15. (Rejected and On Appeal) The process of claim 13 wherein the active substance having substrate activity comprises at least one protein or protein hydrolyzate, or combinations thereof.
16. (Rejected and On Appeal) The process of claim 13 wherein the active substance having substrate activity comprises at least one protein or protein hydrolyzate of elastin, collagen, keratin, silk, soya, almond, pea, alga, potato, or wheat, or combinations thereof.
17. (Rejected and On Appeal) The process of claim 16 wherein the active substance comprises casein, soya protein or wheat protein, or combinations thereof.
18. (Rejected and On Appeal) The process of claim 13 wherein the active substance

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having substrate activity comprises a substance synthetically functionalized with an H₂N-R group or an H₂N-(CO)-R' group, wherein R and R' represent an unbranched C₁₋₈ alkylene group.

19. (Rejected and On Appeal) The process of claim 18 wherein the synthetically functionalized substance has at least one H₂N-(CH₂)₄ group.

20. (Rejected and On Appeal) The process of claim 18 wherein the synthetically functionalized substance has at least one H₂N-(CO)-CH₂-CH₂ group.

21. (Rejected and On Appeal) The process of claim 13 wherein the enzyme having transglutaminase activity and the active substance having substrate activity are applied simultaneously to the keratin fibers.

22. (Rejected and On Appeal) The process of claim 13 wherein the enzyme having transglutaminase activity, and the active substance having substrate activity are applied successively in any order.

23. (Rejected and On Appeal) The process of claim 13 wherein the enzyme having transglutaminase activity is contacted with the keratin fibers for a contact time of 3 minutes to 120 minutes.

24. (Rejected and On Appeal) A process for setting keratin fibers comprising
(a) applying to keratin fibers at least one enzyme having transglutaminase activity and at least one active substance having substrate activity for the enzyme; and
(b) setting the keratin fibers.

25. (Rejected and On Appeal) The process of claim 24 wherein the active substance having substrate activity comprises at least one protein or protein hydrolyzate of elastin, collagen, keratin, silk, soya, almond, pea, alga, potato, or wheat, or combinations thereof.

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26. (Rejected and On Appeal) The process of claim 25 wherein the active substance comprises casein, soya protein or wheat protein, or combinations thereof.

27. (Rejected and On Appeal) The process of claim 26 wherein the enzyme having transglutaminase activity comprises a calcium-independent transglutaminase.

9. EVIDENCE APPENDIX

None.

10. LIST OF REFERENCES

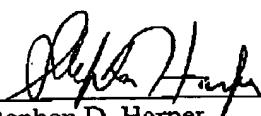
U.S. Patent No. 6,274,364 to Bernard et al.

U.S. Patent No. 6,051,033 to McDevitt et al.

CONCLUSION

For the reasons stated above, the Examiner's final rejection of claims 13-27 should be reversed. The Commissioner is hereby authorized to charge the Appeal Brief Fee of \$500.00 to Deposit Account 01-1250. Order No. 05-0202. Should any fees be due for entry and consideration of this Brief that have not been accounted for, the Commissioner is authorized to charge them to Deposit Account No. 01-1250.

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